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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,677	10/06/2004	Mark Parrington	API-01-20-US	4967

7590 11/17/2008
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One Discovery Drive
Swiftwater, PA 18370

EXAMINER

AEDER, SEAN E

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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11/17/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,677	Applicant(s) PARRINGTON ET AL.	
	Examiner SEAN E. AEDER	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 and 44 is/are allowed.
- 6) ☒ Claim(s) 1-30, 38-43, and 45-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The Amendments and Remarks filed 9/20/08 in response to the Office Action of 4/21/08 are acknowledged and have been entered.

Claims 51-66 have been added by Applicant.

Claims 1-30, 36, and 38-66 are pending.

Claims 1, 26, 36, 38, 44, and 45 have been amended by Applicant.

Claims 1-30, 36, and 38-66 are currently under examination.

The following Office Action contains NEW GROUNDS of rejections.

Objection Withdrawn

The objection to the specification is withdrawn.

Rejections Withdrawn

All previous rejections are withdrawn.

Information Disclosure Statement

In reply to Applicants query regarding an information disclosure statement filed 11/14/07, the Office does not have any record of an information disclosure statement filed 11/14/07.

Warning

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Applicant is advised that should claim 38 be found allowable, claim 51 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

New Rejections

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-30, 38-43, 51, and 53-66 are rejected under 35 U.S.C. 101 because claims 1-30, 38-43, 51, and 53-66, as written, does not sufficiently distinguish over nucleic acids as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The term "expression vector" does not indicate the hand of man is required. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 52-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 52-66 are rejected as indefinite for reciting highly stringent hybridization conditions, as the specification does not distinctly define the limitations of such conditions. The specification teaches "moderately stringent conditions" refers to conditions under which a DNA duplex with a greater degree of base pair mismatching than could occur under "highly stringent conditions" (see lines 21-24 on page 7). The specification teaches that exemplary moderately stringent conditions are hybridization in 0.0115 M sodium chloride, 0.0015 M sodium citrate at 50-65 degrees Celsius (see lines 24-26 on page 7). However, highly stringent conditions are not *defined* by the claims and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This rejection can be obviated by distinctly defining the conditions, *including washing conditions*, under which highly stringent conditions are practiced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 52-54, 56, 58-59, 61, and 63-66 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claims 52-54, 56, 58-59, 61, and 63-66 are drawn to products comprising nucleic acid molecules that comprise a nucleic acid sequence which hybridizes under highly stringent conditions to nucleotides 429-1488, 429-876, or 891-1488 of SEQ IDNO:28. Descriptions of products comprising nucleic acid molecules that comprise a nucleic acid sequence which hybridizes under highly stringent conditions to nucleotides 429-1488, 429-876, or 891-1488 of SEQ IDNO:28 are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-50 and 52-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti et al (US Patent 5,833,975; 11/10/98).

The claims further encompass compositions comprising expression vectors comprising nucleic acid sequences which hybridize to fragments of SEQ ID NO:28 (see claims 52-66).

Paoletti et al teaches ALVAC poxvirus vectors comprising CEA antigen-encoding SEQ ID NO:145, which shares greater than 80% homology with instant SEQ ID NO:28, and the full complement thereof (see abstract and sequence comparison below, in particular). Paoletti et al further teaches said vectors further comprising a nucleic acid sequences including the costimulatory molecule B7.1 (line 58 of column 14, in particular). Paoletti et al further teaches compositions comprising said vectors and pharmaceutically acceptable carriers (see line 22 of column 8, in particular). In regards to instant claims 45-50, it is noted that the nucleic acids of SEQ ID NO:145 includes all nucleic acids of 421-1490 of SEQ ID NO:28 (A, T, G, and C). Further, due to a high degree of shared homology, the complement of SEQ ID NO:145 found in the product of Paoletti et al, would bind under highly stringent conditions to nucleotides 429-1488, nucleotides 429-876, nucleotides 891-1488, a AclI-BamHI fragment, and a BamHI-Bsu361 fragment of instant SEQ ID NO:28.

Comparison of instant SEQ ID NO:28 and SEQ ID NO:145 of Paoletti et al:

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Query Match          80.6%;  Score 1697.8;  DB 2;  Length 2349;
  Best Local Similarity  88.1%;  Pred. No. 0;
  Matches 1859;  Conservative    0;  Mismatches  247;  Indels    3;  Gaps
1;

QY          1  ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC  60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          184 ATGGAGTCTCCCTCGGCCCCCTCCCCACAGATGGTGCATCCCCTGGCAGAGGCTCCTGCTC
243
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Qy 120	61	ACAGCCTCACTTCTAACCTTCTGGAACCCGCCCACCACTGCCAAGCTCACTATTGAATCC
Db 303	244	ACAGCCTCACTTCTAACCTTCTGGAACCCGCCCACCACTGCCAAGCTCACTATTGAATCC
Qy 180	121	ACGCCGTTCAATGTGCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCCACAATCTGCCCCAG
Db 363	304	ACGCCGTTCAATGTGCGCAGAGGGGAAGGAGGTGCTTCTACTTGTCCACAATCTGCCCCAG
Qy 240	181	CATCTTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
Db 423	364	CATCTTTTTGGCTACAGCTGGTACAAAGGTGAAAGAGTGGATGGCAACCGTCAAATTATA
Qy 300	241	GGATATGTAATAGGAACCTCAACAAGCTACCCCAGGGCCCGCATACAGTGGTCGAGAGATA
Db 483	424	GGATATGTAATAGGAACCTCAACAAGCTACCCCAGGGCCCGCATACAGTGGTCGAGAGATA
Qy 360	301	ATATACCCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
Db 543	484	ATATACCCCAATGCATCCCTGCTGATCCAGAACATCATCCAGAATGACACAGGATTCTAC
Qy 420	361	ACCCTACACGTCATAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
Db 603	544	ACCCTACACGTCATAAAGTCAGATCTTGTGAATGAAGAAGCAACTGGCCAGTTCCGGGTA
Qy 480	421	TACCCGGAACCTCCCTAAGCCTTCTATTAGCTCCAATAATAGTAAGCCTGTCTGAAGACAAA
Db 663	604	TACCCGAGCTGCCCAAGCCCTCCATCTCCAGCAACAACCTCCAAACCCGTGGAGGACAAG
Qy 540	481	GATGCCGTCGCTTTTACATGCGAGCCCGAAACTCAAGACGCAACATATCTCTGGTGGGTG
Db 723	664	GATGCTGTGGCCTTCACCTGTGAACCTGAGACTCAGGACGCAACCTACCTGTGGTGGGTA
Qy 600	541	AACAACCAGTCCCTGCCTGTGTCCCCTAGACTCCAACCTCAGCAACGGAAATAGAACTCTG
Db 783	724	AACAATCAGAGCCTCCCGGTCAGTCCCAGGCTGCAGCTGTCCAATGGCAACAGGACCCTC

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Qy	660	601	ACCCTGTTTTAACGTGACCAGGAACGACACAGCAAGCTACAAATGCGAAACCCAAAATCCA
Db	843	784	ACTCTATTCAATGTGACACAAGAAATGACACAGCAAGCTACAAATGTGAAACCCAGAACCCA
Qy	720	661	GTCAGCGCCAGGAGGTCTGATTCAAGTGATTCTCAACGTGCTTTACGGACCCGATGCTCCT
Db	903	844	GTGAGTGCCAGGCGCAGTGATTCAAGTCATCCTGAATGTCTCTATGGCCCGGATGCCCCC
Qy	780	721	ACAATCAGCCCTCTAAACACAAGCTATAGATCAGGGGAAAATCTGAATCTGAGCTGTCAT
Db	963	904	ACCATTTCCCTCTAAACACATCTTACAGATCAGGGGAAAATCTGAACCTCTCCTGCCAC
Qy	840	781	GCCGCTAGCAATCCTCCCGCCCAATACAGCTGGTTTGTCATGGCACTTTCCAACAGTCC
Db	1023	964	GCAGCCTCTAACCACCTGCACAGTACTCTTGGTTTGTCATGGGACTTTCCAGCAATCC
Qy	900	841	ACCCAGGAAGTGTTCATTCCCAATATTACCGTGAACAATAGTGGATCCTACACGTGCCAA
Db	1083	1024	ACCCAAGAGCTCTTTATCCCCAACATCACTGTGAATAATAGTGGATCCTATACGTGCCAA
Qy	957	901	GCTCACAATAGCGACACCGGACTCAACCGCACAACCGTGACGACGATTACCGTGTAT---
Db	1143	1084	GCCCATAACTCAGACACTGGCCTCAATAGGACCACAGTCACGACGATCACAGTCTATGCA
Qy	1017	958	GAGCCACCAAACCATTCATAACTAGTAACAATTCTAACCCAGTTGAGGATGAGGACGCA
Db	1203	1144	GAGCCACCAAACCCCTTCATCACCAGCAACAACCTCCAACCCCGTGGAGGATGAGGATGCT
Qy	1077	1018	GTTGCATTAACCTTGTGAGCCAGAGATTCAAAATACCACTTATTTATGGTGGGTCAATAAC
Db	1263	1204	GTAGCCTTAACCTGTGAACCTGAGATTGAGAACACAACCTACCTGTGGTGGGTAAATAAT
Qy	1137	1078	CAAAGTTTGCCGGTTAGCCACGCTTGCAGTTGTCTAATGATAACCGCACATTGACACTC
Db	1323	1264	CAGAGCCTCCCGGTGAGTCCCAGGCTGCAGCTGTCCAATGACAACAGGACCCCTCACTCTA

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Qy 1737	1678	GTCACAAGAAATGACGCAAGAGCCTATGTATGTGGAATCCAGAACTCAGTGAGTGCAAAC
Db 1923	1864	GTCACAAGAAATGACGCAAGAGCCTATGTATGTGGAATCCAGAACTCAGTGAGTGCAAAC
Qy 1797	1738	CGCAGTGACCCAGTCACCCTGGATGTCCTCTATGGGCCGGACACCCCCATCATTTCCCCC
Db 1983	1924	CGCAGTGACCCAGTCACCCTGGATGTCCTCTATGGGCCGGACACCCCCATCATTTCCCCC
Qy 1857	1798	CCAGACTCGTCTTACCTTTTCGGGAGCGGACCTCAACCTCTCCTGCCACTCGGCCTCTAAC
Db 2043	1984	CCAGACTCGTCTTACCTTTTCGGGAGCGAACCTCAACCTCTCCTGCCACTCGGCCTCTAAC
Qy 1917	1858	CCATCCCCGCAGTATTCTTGGCGTATCAATGGGATACCGCAGCAACACACACAAGTTCTC
Db 2103	2044	CCATCCCCGCAGTATTCTTGGCGTATCAATGGGATACCGCAGCAACACACACAAGTTCTC
Qy 1977	1918	TTTATCGCCAAAATCACGCCAAATAATAACGGGACCTATGCCTGTTTTGTCTCTAACTTG
Db 2163	2104	TTTATCGCCAAAATCACGCCAAATAATAACGGGACCTATGCCTGTTTTGTCTCTAACTTG
Qy 2037	1978	GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAAC TTCT
Db 2223	2164	GCTACTGGCCGCAATAATTCCATAGTCAAGAGCATCACAGTCTCTGCATCTGGAAC TTCT
Qy 2097	2038	CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT
Db 2283	2224	CCTGGTCTCTCAGCTGGGGCCACTGTCGGCATCATGATTGGAGTGCTGGTTGGGGTTGCT
Qy	2098	CTGATATAG 2106
Db	2284	CTGATATAG 2292

Allowable Subject Matter

Claims 36 and 44 are allowed.

Summary

Claims 1-30, 38-43, and 45-66 are rejected.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Examiner, Art Unit 1642

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